

US Clinical Studies with the Epik for E-Lasik

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Moria

Epi-Lasik and Lamellar Surgery

ESCRS

Paris 18 Sept, 2004

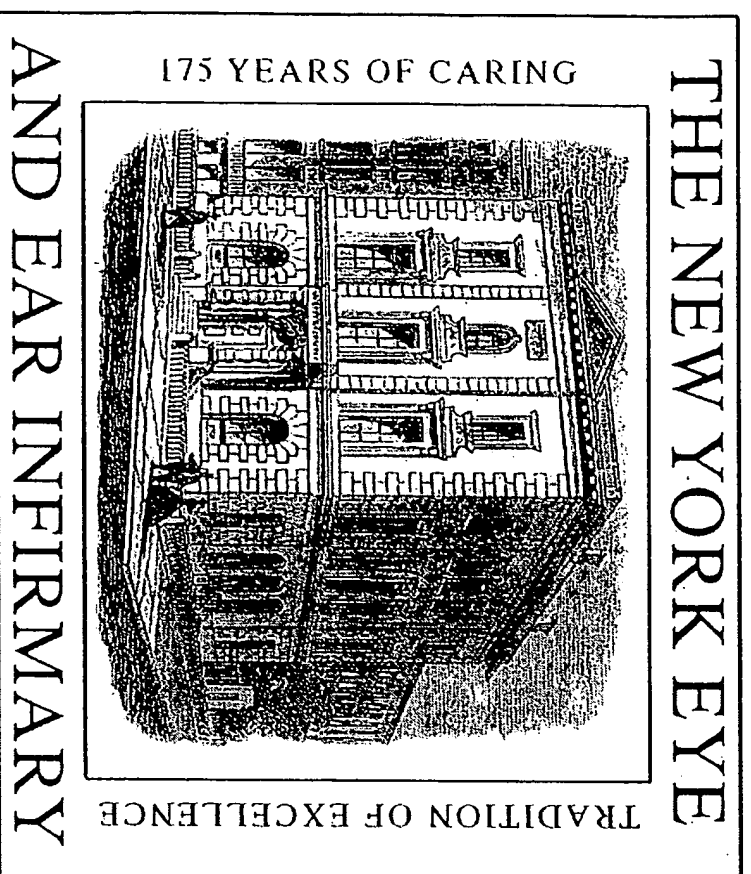
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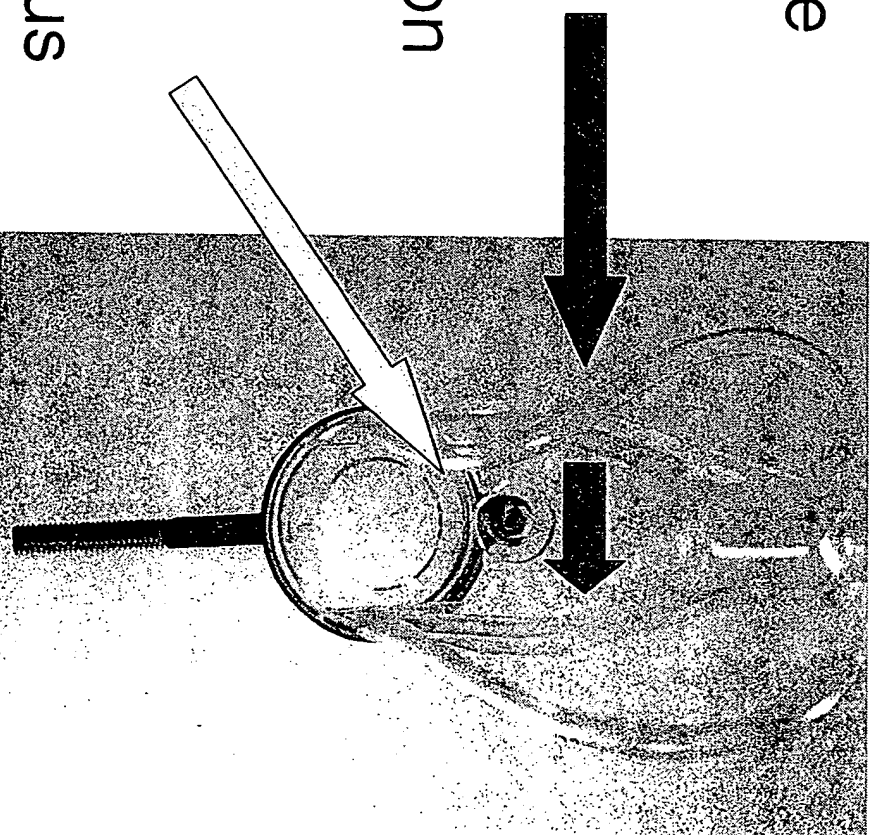
Intra-stromal vs. sub-epithelial Ablation



- Common Goals of Refractive Surgery
 - Fast visual recovery
 - Minimal Pain
 - Long term stability
- LASIK vs Epi Lasik
 - Biomechanical flap risks
 - Ectasia, striae
 - Biochemical healing risks
 - Apoptosis, scarring, irregular collagen formation

Moria Epik Design

- Based on One Use disposable microkeratome
- Dual suction ports maintain lid position
- Up-top adjustable stop avoids problems of short flaps due to canthus



Moria EpiK Design



- Available as:
- Turbine driven manual
- Motor driven automated
 - Drive mechanism is protected from lids



Mechanism of Action Moria Epik

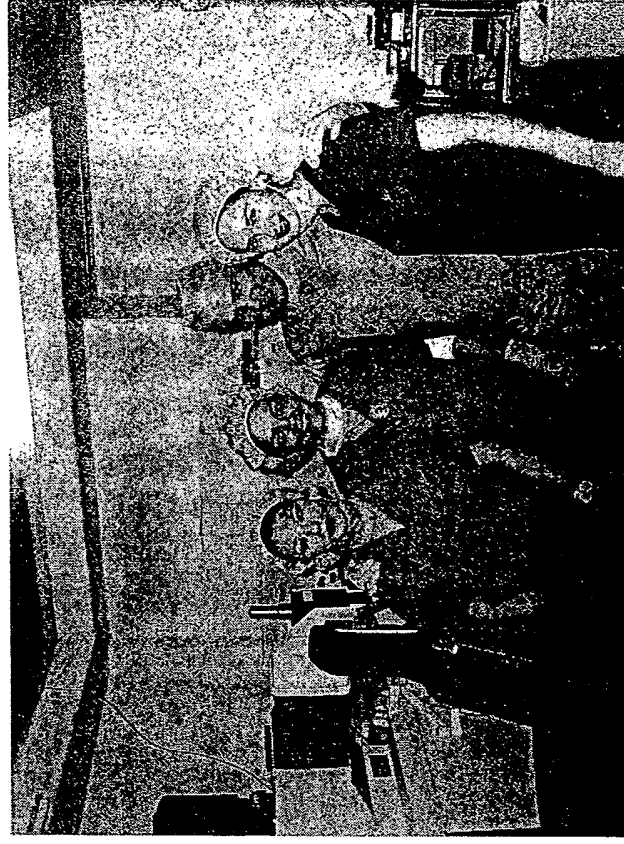
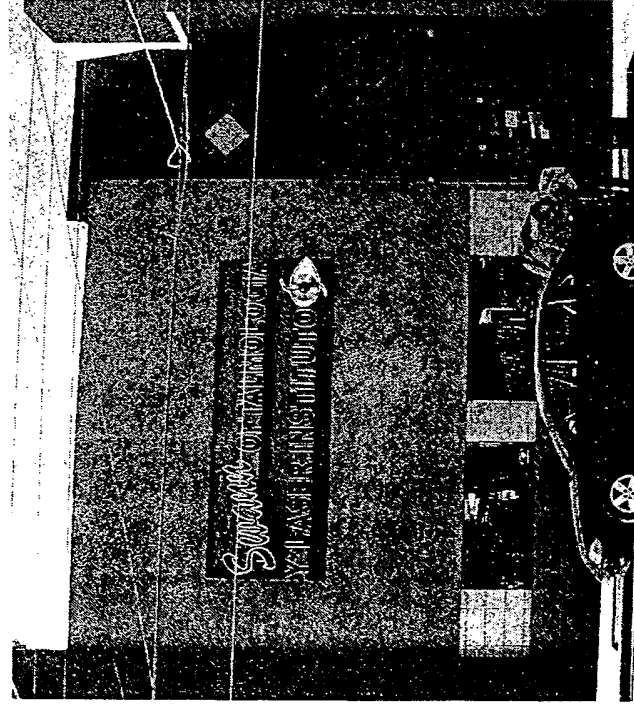


- ✦ Precision machining of the metal blade produces uniformly and reproducibly “blunt” edge”
- ✦ Angle of blade to epithelium allows for cleavage of the epithelial layer instead of cutting
- ✦ Cleavage follows along plane of least resistance by separating and rupturing this plane
- ✦ Cleavage at the level of the basement membrane appears to allow for a viable epithelial layer
- ✦ Implication of better wound healing
 - ✦ Less apoptosis (more stable result)
 - ✦ Less pain
 - ✦ More rapid visual recovery

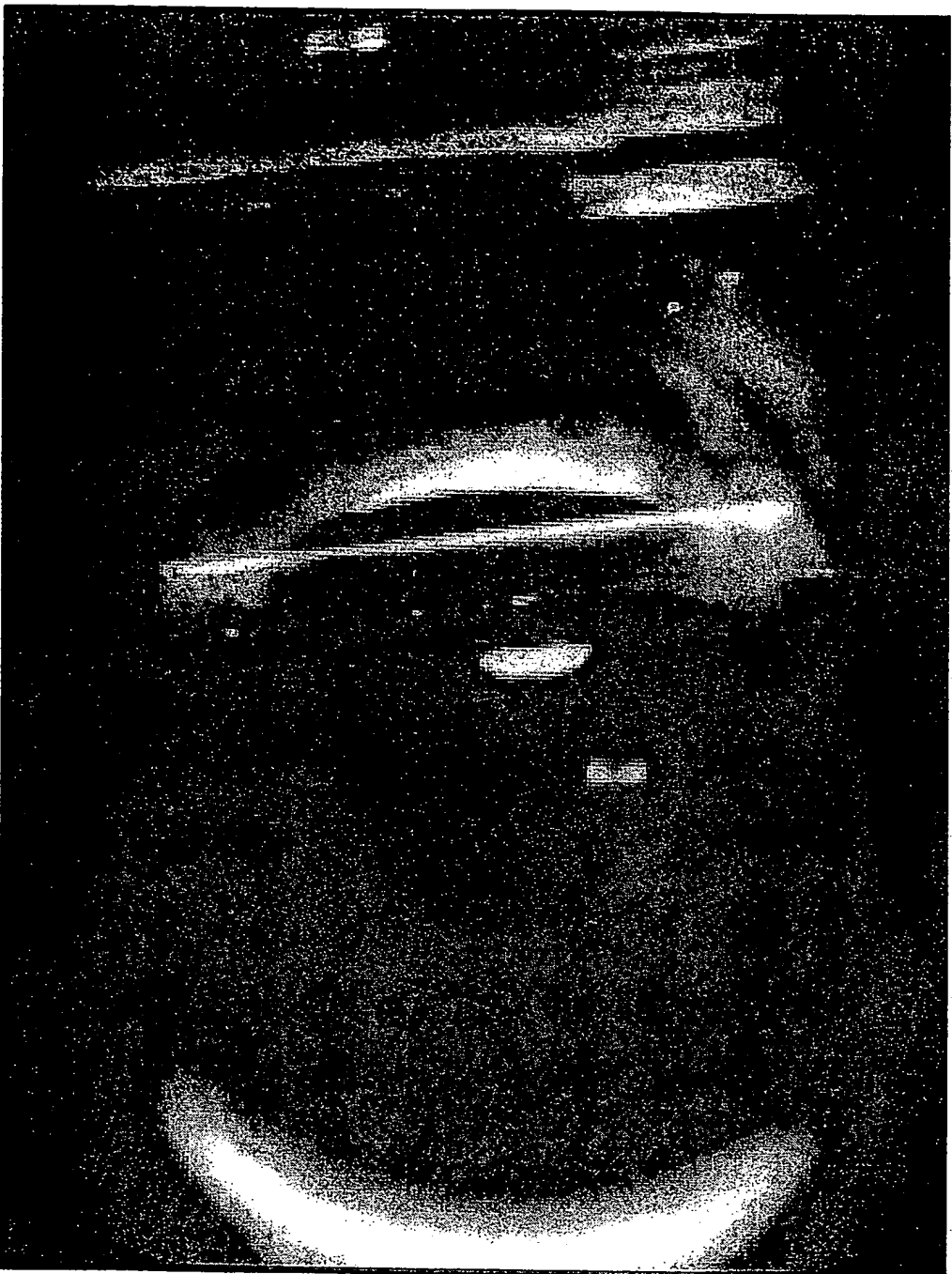
First cases in Mexico



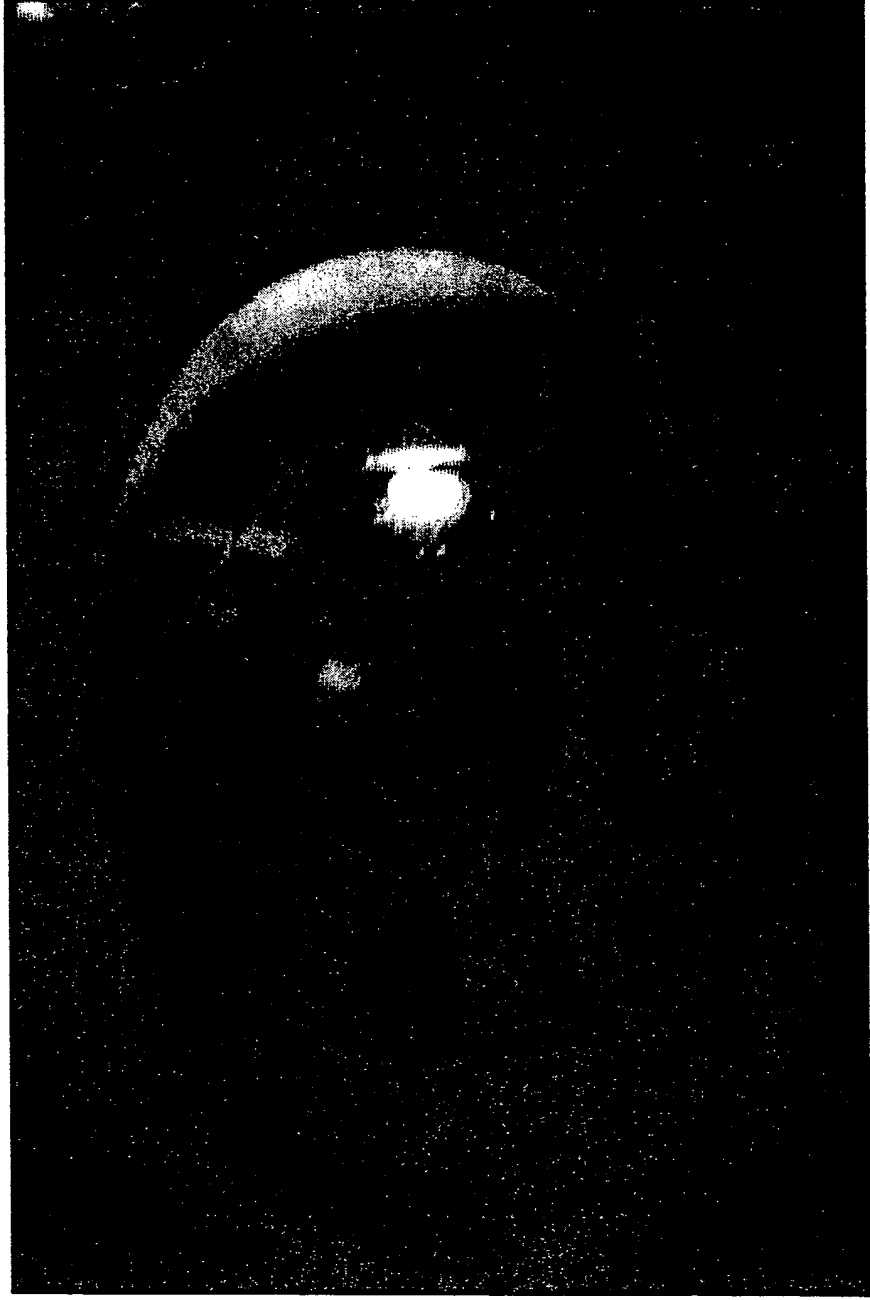
Swanson Ophthalmology and Laser Institute



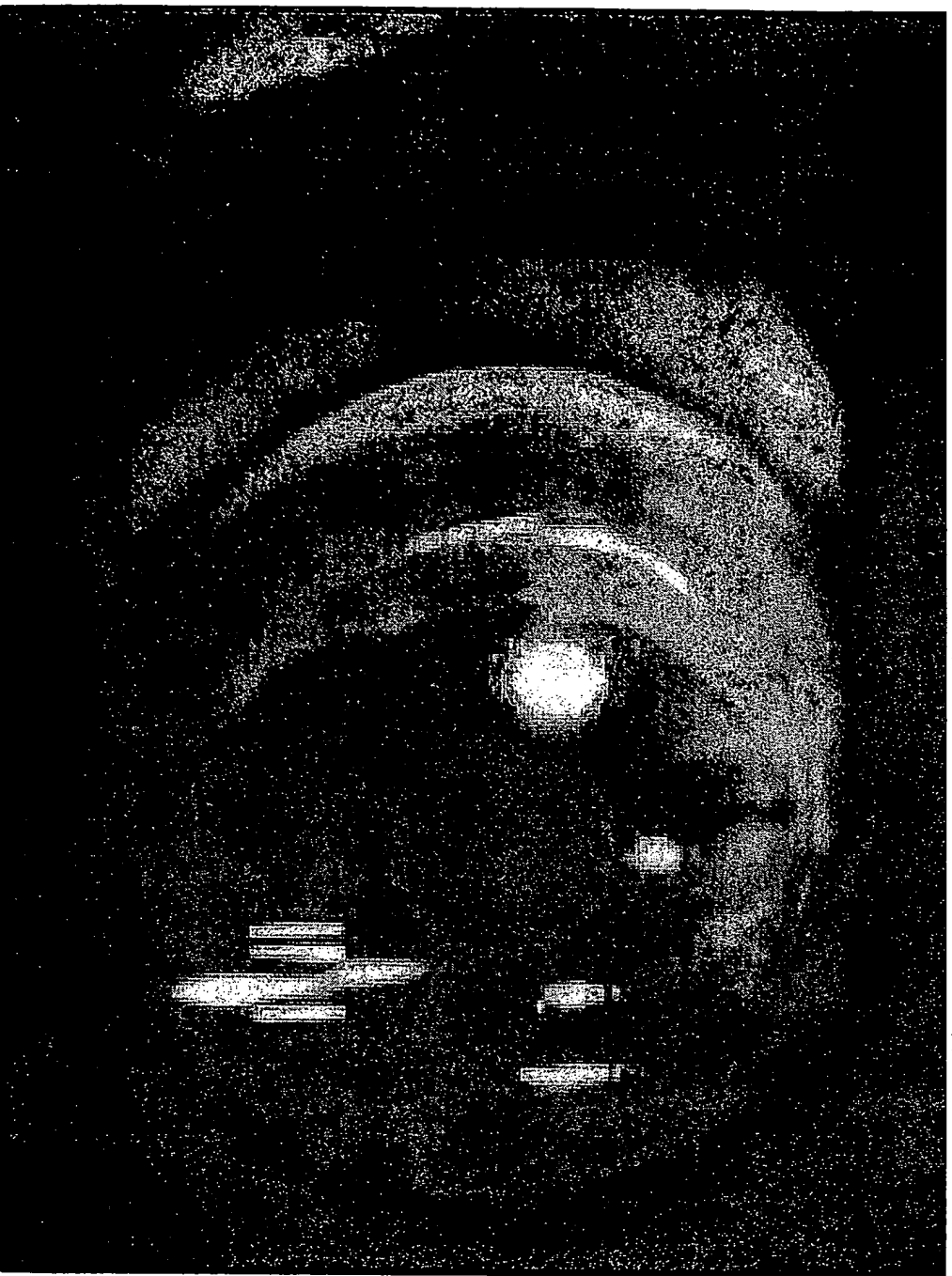
Automated Epik flap generation



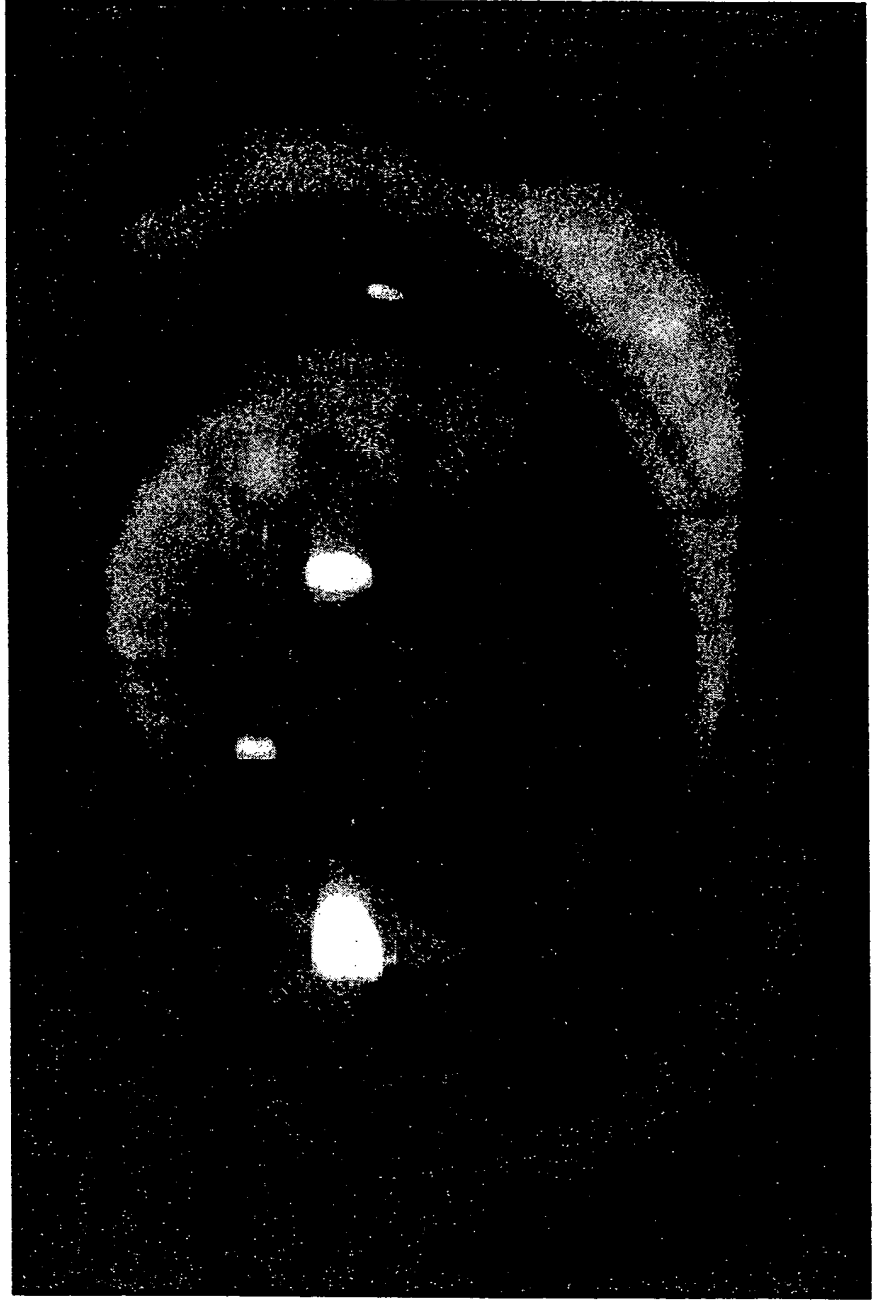
Automated EpiK flap generation



Automated Epik flap replacement



Automated EpiK flap replacement



USA experience



- New York Eye and Ear Infirmary
 - IRB approval June 2004
- Currently 16 eyes with minimum 1 month follow-up

USA Results: -1 Ring (surg pref)

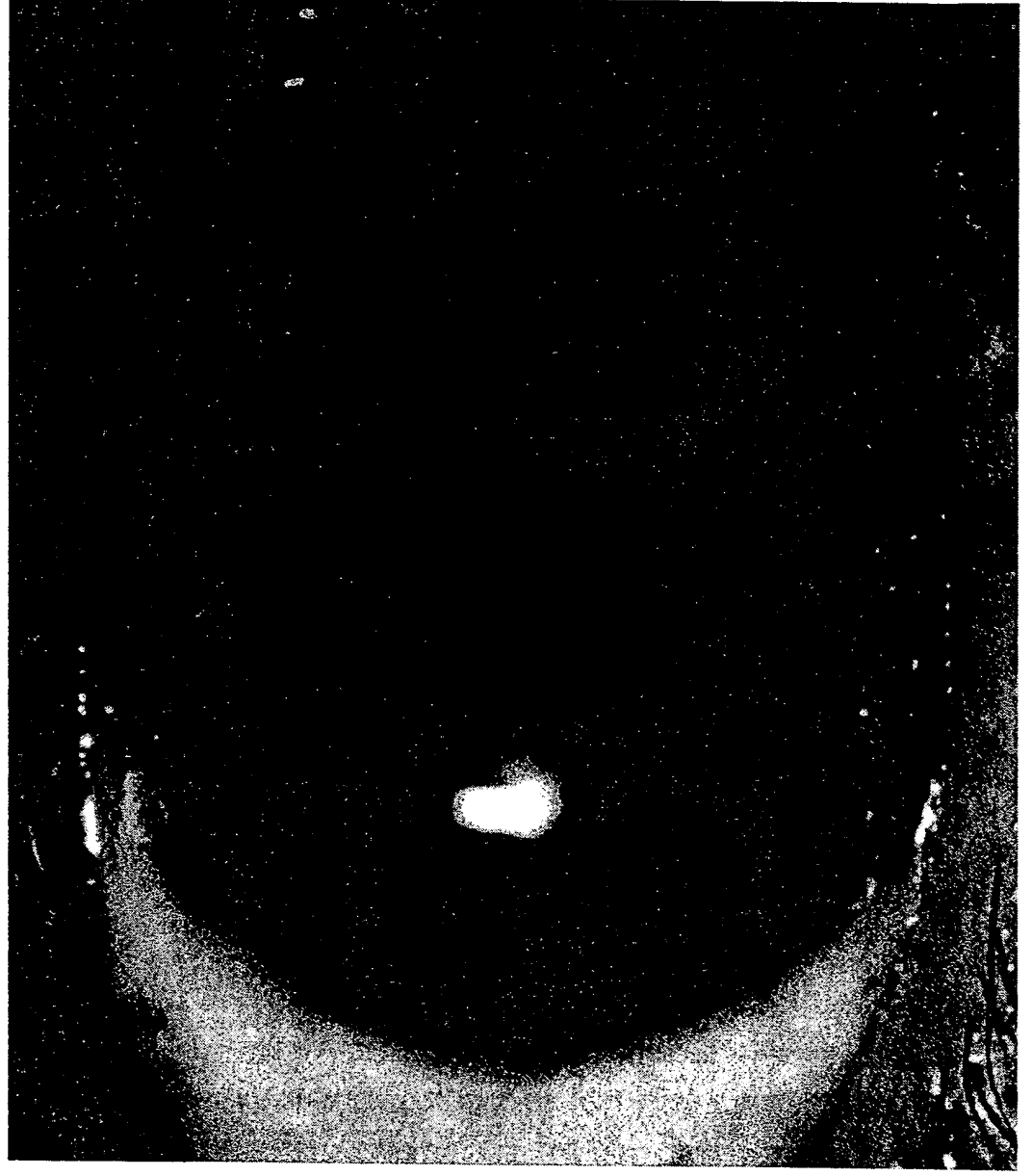
	Mean	Std Dev	Min	Max
Sph Rx	-4.5	2.9	-0.75	-9.00
Cyl Rx	-0.84	0.75	0.00	-2.75
Thick	52.3	9.3	38	79
Hinge	4.7	1.3	3.1	7.6
Vertical	9.2	0.2	9.0	9.5
Horizontal	8.0	0.4	7.3	8.6
Horiz K	43.75	1.5	40.5	45.75
Vert K	44.61	1.3	43	47

Surgical Anatomy US and Mexico

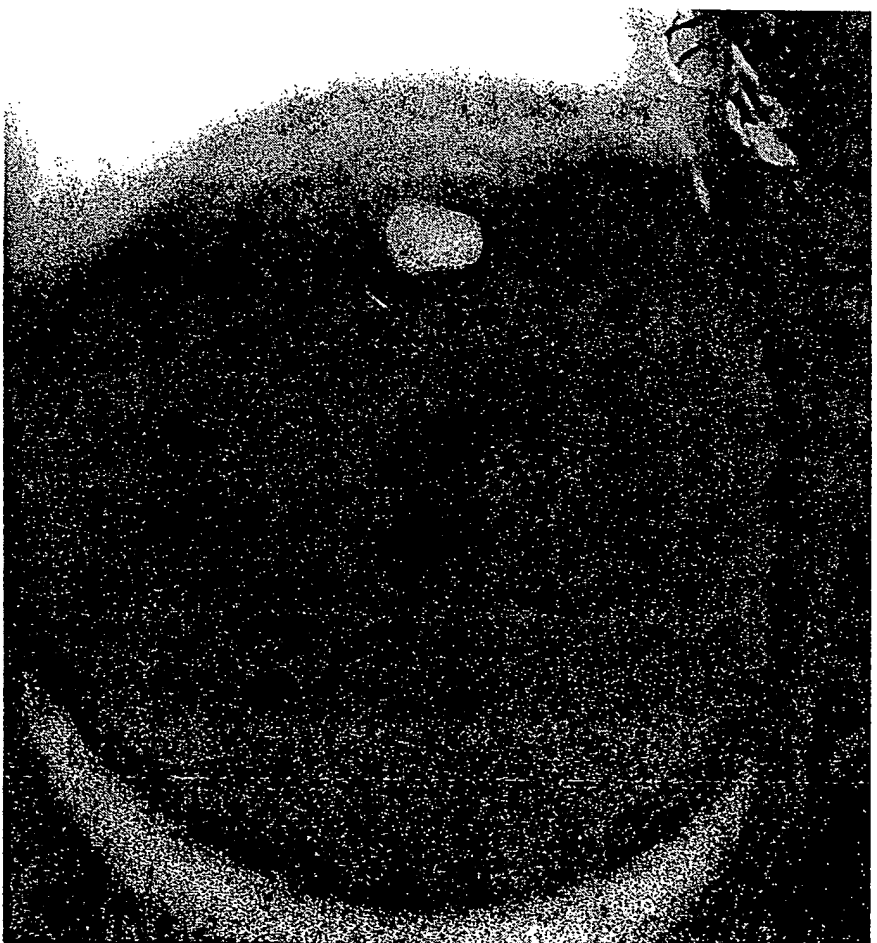
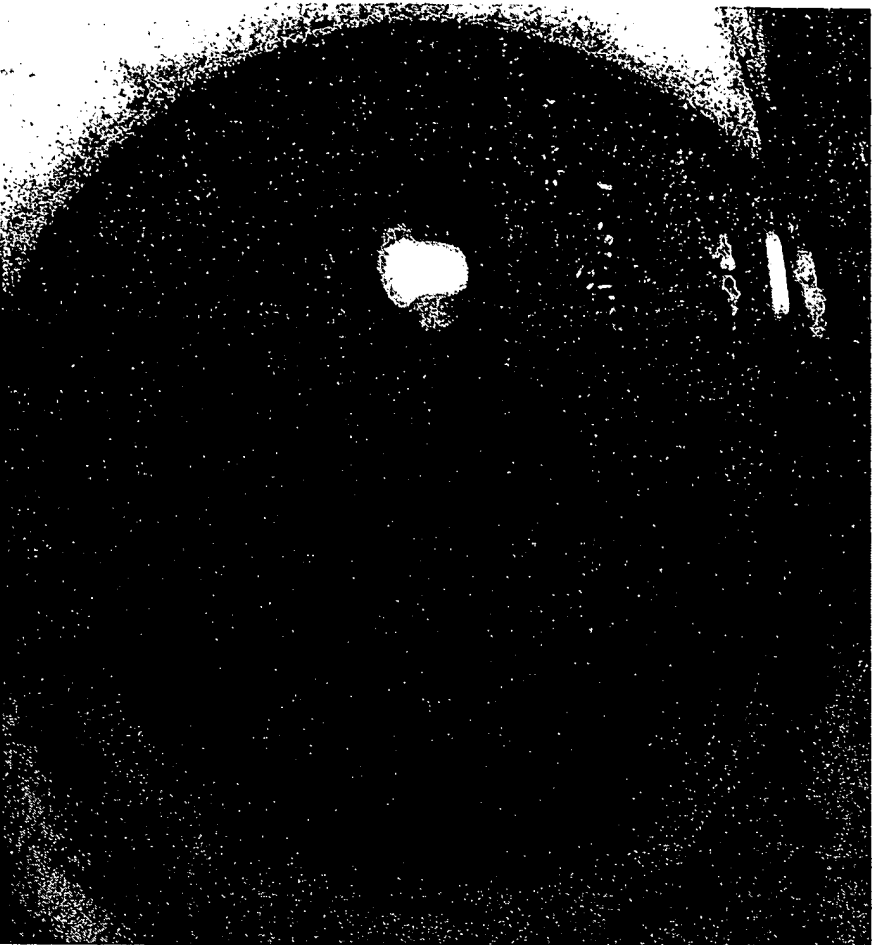


- Edge quality 97.5% excellent
- Bed quality 97.5% excellent
- Epithelial integrity 100% excellent
- Epithelial stretch 100% good
- Interface 97.5% excellent

Post-op Day One

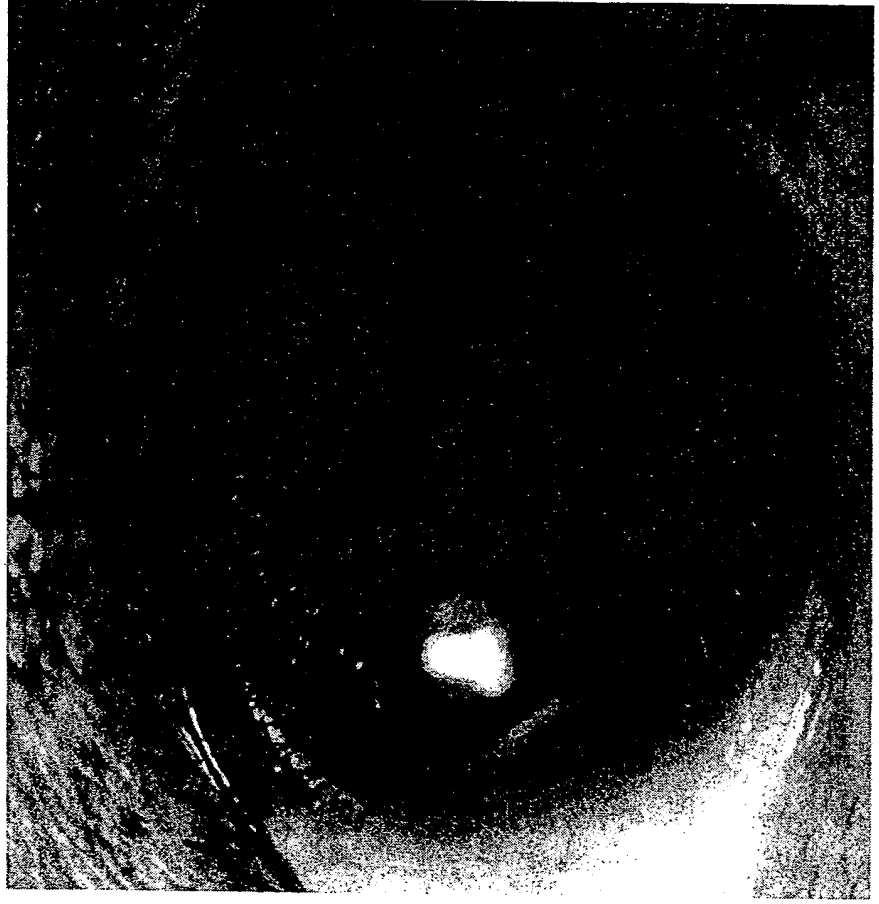


Post-op Day Two



MANUAL PASS

Post-op Day Three



US Pain Level (0=none 10=Most)



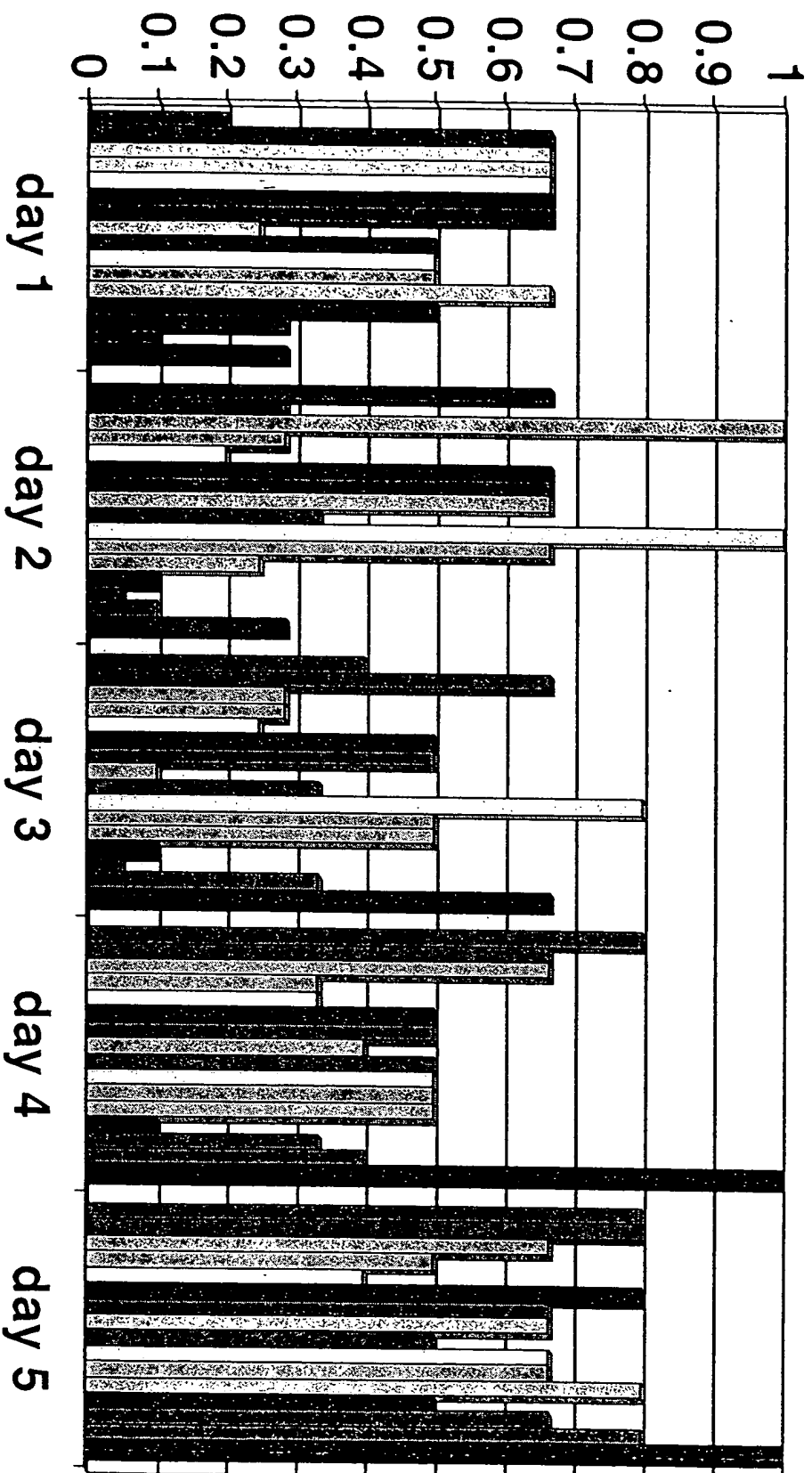
	Mean	Std Dev	Min	Max
Evening	3.5	3.8	0	10
Day 1	1.0	1.3	0	4
Day 2	0.7	0.7	0	2
Day 3	0.7	1.6	0	6
Day 4	0	0	0	0

US Visual Acuity

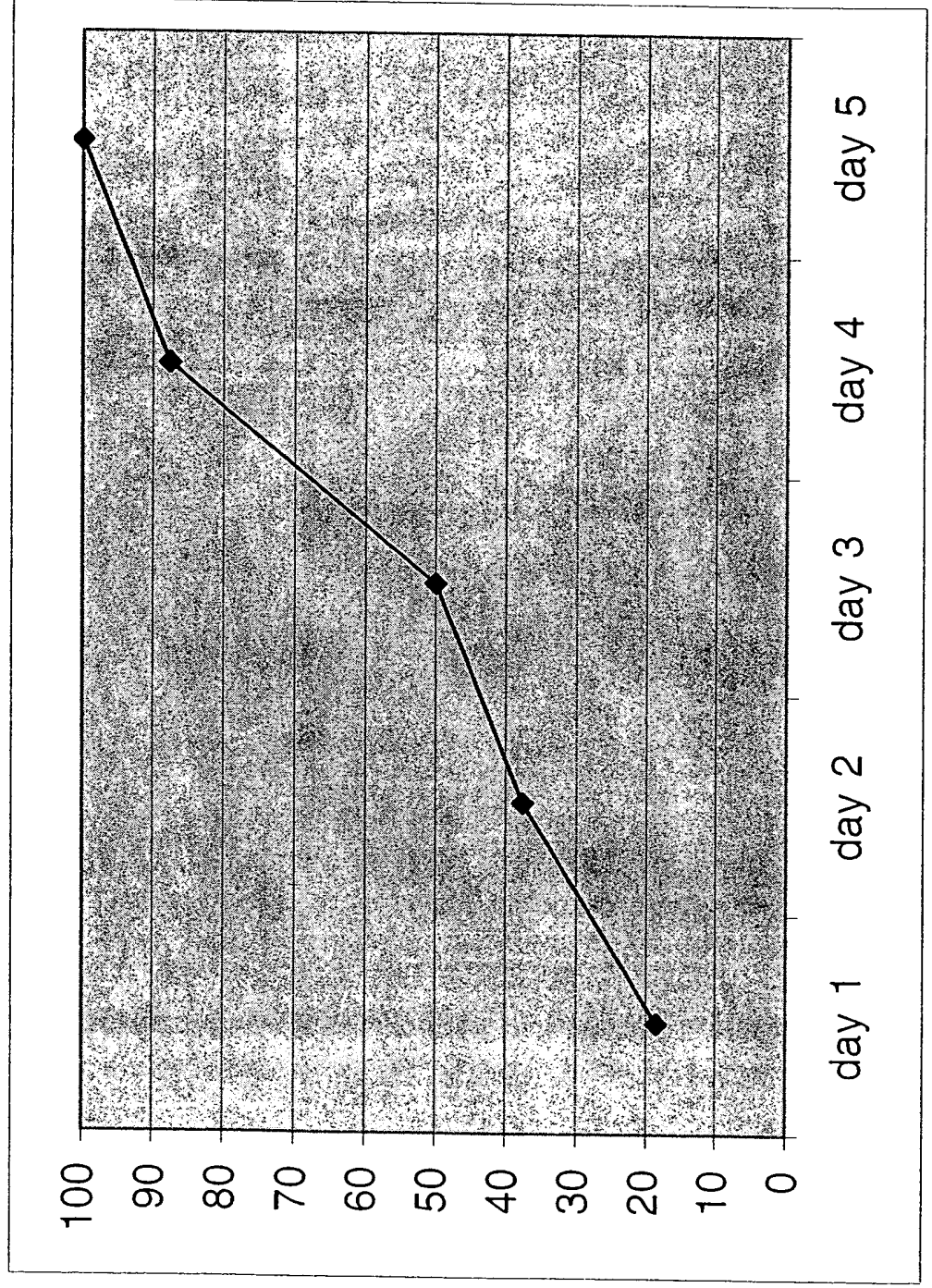


	Mean	Min	Max
Day 1	0.5	0.1	0.67
Day 2	0.5	0.05	1.0
Day 3	0.5	0.05	0.8
Day 4	0.5	0.1	1.0
Day 5	0.67	0.4	1.0

US Post-op Acuity



Percentage able to return to work



Challenges of Epik



- Thin and delicate flap is easily damaged if mis-handled
- Slow and wet technique seems most physiologic

Potential Advantages of EpiK



- Biomechanical flap risks of LASIK such as ectasia and striae may not be amenable to improvement
- Biochemical healing risks such as apoptosis, scarring and irregular collagen formation along with rapid and minimally painful return to good vision may be more easily controlled



Thank you for your attention

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Epi-Lasitome has positive results in Europe

Gebauer Medizintechnik (Neuhausen, Germany) announced positive clinical results for the first 100 Epi-LASIK patients treated in Europe using its minimally invasive, alcohol free Epi-Lasitome. The Epi-Lasitome has received the European CE Mark, and based on its positive clinical evaluation, Gebauer has begun its commercial introduction in several European countries. The company plans to file a 510(k) premarket notification submission with the Food and Drug Administration within the next 60 days seeking marketing clearance in the United States. "I was extremely pleased with the ease with which the Epi-Lasitome created an epithelial flap without incident and without the use of alcohol or other chemicals. The clinical results were excellent," said lead clinical investigator Chris P. Lohmann, M.D., University Eye Clinic, Regensburg, Germany. "Six of the first 100 patients treated were prior LASEK re-treatments. Making the Epi-flap in this group posed no problems and the outcomes were no different."

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